

FORM-PTO-1390
(Rev. 12-29-99)

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTORNEY'S DOCKET NUMBER

**TRANSMITTAL LETTER TO THE UNITED STATES
DESIGNATED/ELECTED OFFICE (DO/EO/US)
CONCERNING A FILING UNDER 35 U.S.C. 371**

018413-331

U.S. APPLICATION NO. (If known, see 37 C.F.R. 1.5)

Unassigned **09/806946**INTERNATIONAL APPLICATION NO.
PCT/US99/29329INTERNATIONAL FILING DATE
9 December 1999 (09.12.99)PRIORITY DATE CLAIMED
10 December 1998 (10.12.98)TITLE OF INVENTION
IMPROVED GUIDEWIREAPPLICANT(S) FOR DO/EO/US
ASHBY, Mark P., et al.

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☐ This is an express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and the PCT Articles 22 and 39(1).
4. ☒ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
 - a. ☒ is transmitted herewith (required only if not transmitted by the International Bureau).
 - b. ☒ has been transmitted by the International Bureau.
 - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US)
6. ☐ A translation of the International Application into English (35 U.S.C. 371(c)(2)).
7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
 - a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
 - b. ☐ have been transmitted by the International Bureau.
 - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
 - d. ☐ have not been made and will not be made.
8. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11. to 16. below concern other document(s) or information included:

11. ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☐ A FIRST preliminary amendment.
- ☐ A SECOND or SUBSEQUENT preliminary amendment.
14. ☐ A substitute specification.
15. ☐ A change of power of attorney and/or address letter.
16. ☒ Other items or information:
PTO Form 1449, Return Postcard and International Publication No. WO 00/33984

U.S. APPLICATION NO. (If known, / 09/87 C.F.R. 1.55)
Unassigned

09/87 806946

INTERNATIONAL APPLICATION NO.
PCT/US99/29329ATTORNEY'S DOCKET NUMBER
018413-331

17. <input checked="" type="checkbox"/> The following fees are submitted:				CALCULATIONS		PTO USE ONLY	
Basic National Fee (37 CFR 1.492(a)(1)-(5)): Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO \$1,000.00 (960) International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO \$860.00 (970) International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO \$710.00 (958) International preliminary examination fee paid to USPTO (37 CFR 1.482) but all claims did not satisfy provisions of PCT Article 33(1)-(4) \$690.00 (956) International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(1)-(4) \$100.00 (962) ENTER APPROPRIATE BASIC FEE AMOUNT =				\$ 690.00			
Surcharge of \$130.00 (154) for furnishing the oath or declaration later than 20 <input type="checkbox"/> 30 <input checked="" type="checkbox"/> months from the earliest claimed priority date (37 CFR 1.492(e)).				\$ 130.00			
Claims		Number Filed	Number Extra	Rate			
Total Claims		7 -20 =	0	X\$18.00 (966)		\$ 0	
Independent Claims		1 -3 =	0	X\$80.00 (964)		\$ 0	
Multiple dependent claim(s) (if applicable)				+ \$270.00 (968)		\$ 0	
TOTAL OF ABOVE CALCULATIONS =				\$ 820.00			
Reduction for 1/2 for filing by small entity, if applicable (see below).				\$ 410.00		-	
SUBTOTAL =				\$ 410.00			
Processing fee of \$130.00 (156) for furnishing the English translation later than 20 <input type="checkbox"/> 30 <input type="checkbox"/> months from the earliest claimed priority date (37 CFR 1.492(f)).				\$ 0			
TOTAL NATIONAL FEE =				\$ 410.00			
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 (581) per property +				\$ 0			
TOTAL FEES ENCLOSED =				\$ 410.00			
				Amount to be: refunded		\$	
				charged		\$	
a. <input type="checkbox"/> Small entity status is hereby claimed. b. <input checked="" type="checkbox"/> A check in the amount of \$ <u>410.00</u> to cover the above fees is enclosed. c. <input type="checkbox"/> Please charge my Deposit Account No. <u>02-4800</u> in the amount of \$ _____ to cover the above fees. A duplicate copy of this sheet is enclosed. d. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>02-4800</u> . A duplicate copy of this sheet is enclosed. NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status. SEND ALL CORRESPONDENCE TO: SWISS, Gerald F. KREBS, Robert E. BURNS, DOANE, SWECKER & MATHIS, L.L.P. P.O. Box 1404 Alexandria, Virginia 22313-1404 (703) 836-6620							
				SIGNATURE			
				SWISS, Gerald F.			
				NAME			
				30,113			
				REGISTRATION NUMBER			

IMPROVED GUIDEWIRE

BACKGROUND OF THE INVENTION

1. Field of the Invention

The invention relates to medical guidewires.

2. Description of Related Art

Guidewires are well known in the medical art and are used for accessing distal sites within the human body. Common access routes include the digestive tract, urinary tract, and peripheral, cerebral, and visceral vasculature. In use, the guidewire is inserted into a vessel in the patient and maneuvered to a desired target site in the patient's body. Once in place, the guidewire is used to guide other apparatus, such as a catheter, to the target site. This is accomplished by feeding the catheter or other apparatus over the guidewire until the it reaches the target site.

Structurally, guidewires commonly have a core wire having a reduced diameter distal section extending a minority of the guidewire's overall length, and a constant diameter proximal section, extending a majority of the guidewire's overall length. The core sections are manufactured by selecting a single drawn/spooled wire of a diameter equal to the largest diameter section of the desired guidewire, which is generally the proximal section. The spooled wire is then straightened and cut to length, creating a mandrel. The distal segment only of the mandrel is then center-less ground to the desired distal diameters, while the drawn surface of the proximal section is left undisturbed. The core thus produced is further processed into a finished guidewire, including possible coating, or the addition of a helical coil wound over a portion of the guidewire, typically the distal portion.

One important characteristic of a guidewire, especially that used for accessing small, tortuous, distal sites, is the guidewire's ability to transmit one-to-one torque from the proximal portion of the wire extending from the patient's body, to the distal tip of the guidewire. Faithful transmission of torque is important because it determines the ability of the operator to manipulate the implanted, inaccessible distal end of the guidewire by control and manipulation of the unimplanted, proximal end thereof.

For small, long guidewires accessing distal sites through complex/severely tortuous paths, one-to-one torque response is hindered by two major factors. The first of these is whipping of the guidewire, related to the manufacturing limitations associated with straightening and processing a small diameter wire. The second is surface friction over the length of inserted wire associated with the limited ability of the guidewire's drawn surface to be uniformly and durably coated with a desirable friction reducing substance.

Material stiffness and deflection can be explained with reference to FIG. 1 and the following equation:

$$y = (FL^3)/3EI$$

where y is the deflection, F is the force applied, E is Young's modulus for the material used, and I is the moment of inertia (for a bar of circular cross section, $I = D^4/64$, with D being the diameter of the bar).

Assuming that force, length, and cross sectional area are constant, then materials with lower Young's modulus will bend more, or conversely, materials with higher Young's modulus will be stiffer. Similarly, wires with smaller diameters will bend more, or larger forces will cause greater bending. Consequently, the stiffness, or amount of force it takes to bend the wire varies with the fourth power of the diameter of the core wire, and the Young's modulus can be used to predict the usefulness of

different materials. As an example, titanium wire of equal diameter to a stainless steel wire would have 1/4 the stiffness due to the difference in their Young's moduli.

Torsional loads can be modeled in a similar manner. FIG. 2 is analogous to holding a wire at one end and twisting at the other end to cause the tip to turn. The twisting action places the wire under a torque load condition. The applicable equation here is:

$$\phi = TL/GJ$$

where ϕ is the angular deflection, T is the torque, L is the length of the wire, G is the modulus of rigidity, and J is the polar second moment of the area (for a bar of circular cross section, $J = \pi D^4/32$).

For good torque control a material with a high modulus of rigidity will provide less angular displacement (less windup), of the distal tip given that all other variables are constant. Additionally, the second polar moment of area relates the diameter of the wire to torque response. As the diameter decreases the angular deflection, windup, increases at a rate to the fourth power. Consequently, small changes in diameter make large changes in torque control.

As seen from the above, small changes in diameter make a significant change in the functional properties; stiffness and torque control. The smaller the diameter of a wire, the more flexible the wire becomes. This is why the tip of guidewires are tapered to provide the additional flexible region for negotiating tortuous vessels. However, it is to be understood that the decrease in diameter of the wire at the tip also decreases the amount of torque control. Consequently, there is a balance to the design of a guidewire which typically favors increased flexibility at the expense of torque control.

BRIEF SUMMARY OF THE INVENTION

The present invention overcomes whipping problems and coating limitations of prior art guidewires. Whipping problems are overcome by selecting drawn/spooled wire of a diameter greater than the largest diameter section of the desired guidewire. This larger spooled wire is then straightened and cut to length, creating a mandrel. The entire length of the mandrel is then center-less ground to the distal and proximal diameters. The initial larger diameter of this wire ultimately results in a mandrel which overcomes limitations of the straightening process and results in a guidewire which is less prone to whipping and which provides more faithful torque transmission across its length.

A further advantage of the present invention is due to the entire length of the core having a ground surface, as opposed to a very smooth and shiny surface of conventional drawn wire. The ground surface of the proximal section wets-out more easily and uniformly than the drawn surface of prior art guidewire, as well as providing more surface area for coating attachment. This translates to more options of coating materials, more uniform coating distribution, and stronger coating attachments.

Another advantage provided by the present design is improved user interface. This comes by leaving the proximal-most segment of the guidewire uncoated, providing the operator with a surface which is much easier to grasp/torque.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S)

Many advantages of the present invention will be apparent to those skilled in the art with a reading of this specification in conjunction with the attached drawings, wherein like reference numerals are applied to like elements and wherein:

FIG. 1 is a schematic diagram illustrative of a cantilevered beam subjected to bending force;

FIG. 2 is a schematic diagram illustrative of a rod under torque force;

FIG. 3 is a schematic diagram of a spooled wire from which a mandrel in accordance with the invention is made;

FIG. 4 is a schematic diagram of the cut and straightened spooled wire of FIG. 3;

FIG. 5 is a schematic diagram of a shaped mandrel in accordance with the invention;

FIG. 6A is a cross-sectional view taken along line 6A - 6A of FIG. 5;

FIG. 6B is a cross-sectional view of a non-round mandrel in accordance with the invention;

FIG. 7 is a schematic diagram of a coil used in a guidewire in accordance with the invention; and

FIG. 8 is a schematic diagram of a completed guidewire product formed in accordance with the invention.

DETAILED DESCRIPTION OF THE INVENTION

In accordance with the present invention, a guidewire is manufactured using a segment of drawn/spooled wire which is straightened and cut to an appropriate length. The segment, which is initially of a first, constant diameter D_1 , is ground down or otherwise shaped into a mandrel, or core, comprised of one or more segments k having corresponding diameter(s) D_1 - D_k . The diameters D_1 - D_k may vary, but largest of these, or the maximal diameter D_M , is smaller than the initial diameter D_1 . One or more coatings are optionally applied to one or more of the segments. Additionally, a helical coil can be wound around portions of the mandrel, or core, preferably a portion comprising a distalmost segment of the mandrel. FIGS. 3-5, 6A, 6B, 7, and 8 illustrate this process.

FIG. 3 shows a spool 10 of wire 12 conventionally available from various commercial wire manufacturers. The wire 12 can be metallic, such as stainless steel or titanium, or made from other alloys or materials. D_i indicates the diameter of this wire, which is selected in accordance with the contemplated application of the finished guidewire product. It will be appreciated, for instance, that applications in the cerebral vasculature will require relatively small diameters, while those for cardiosurgical applications can have relatively larger diameters.

The wire 12 from spool 10 is then straightened and cut to an appropriate length L , schematically shown in FIG. 4, with length L corresponding generally to the contemplated guidewire application and to the patient size. Subsequently, the wire 12 is preferably center-less ground, but can be otherwise shaped, to form a substantially cylindrical mandrel 14 having one or more segments k of varying diameters, all of which are smaller than the initial diameter D_i of the wire 12. In other words, the maximal diameter D_M of the mandrel is smaller than D_i , or $D_M < D_i$. In FIG. 5, three segments—16, 18 and 20—are shown, having respective diameters D_1 - D_3 , with the inequalities $D_1 < D_i$, $D_2 < D_i$ and $D_3 < D_i$ being applicable. Although as exemplarily shown in FIG. 5 proximal segment 16 has the largest diameter, with those of segments 18 and 20 being progressively smaller, it is within the scope of the invention to have a different relative arrangement of the segments and their corresponding diameters. The lengths of the segments are also functions of the desired application. Typically, the proximalmost segment (16) is about 30 cm in length.

While the segments k of mandrel 14 are described as being generally round in cross section, it is to be understood that other cross-sectional shapes, such as oval or elliptical, can be used for any or all of the segments k of mandrel 14. FIG. 6A illustrates the round cross-sectional shape of segment 20, while FIG. 6B shows an alternative oval cross-sectional shape of a section 20' of a mandrel 14'.

After forming mandrel 14, it may be desirable to helically wind a coil such as coil 22 shown in FIG. 7 over a portion of the mandrel 14. Coil 22 is formed of any suitable material, but is preferably of platinum or other radiopaque material. Coil 22 serves to render the portion of the guidewire to which it is attached visible during surgical procedures, or to impart rigidity and torquability, among other physical characteristics, to the section of the guidewire over which it is wound. As shown in FIG. 8, coil 22 is wound over the distal portion 24 of the resulting guidewire 26, corresponding to section 20 of mandrel 14 (FIG. 5), whose ground down dimensions are selected to accommodate the added thickness of the coil 22 wound thereover. Coil 22 is affixed to the core by soldering and/or adhesive means.

Finally, one or more coatings (not shown) may be applied to the guidewire 26 or to selected portions thereof. To increase friction with the operator's hand and thereby facilitate handling, proximal portion 28 of the guidewire 26 is left uncoated, as compared with the remainder of the guidewire, which is preferably treated with a known lubricious coating such as Teflon™ or other hydrophilic material. It is also known to attach a handle (not shown) at proximal portion 28 to further facilitate handling.

The above are exemplary modes of carrying out the invention and are not intended to be limiting. It will be apparent to those of ordinary skill in the art that modifications thereto can be made without departure from the spirit and scope of the invention as set forth in the following claims.

CLAIMS

1. A method for manufacturing a guidewire having a substantially cylindrical mandrel, said mandrel having one or more segments each having a diameter not exceeding a maximal diameter, the method comprising:

5 providing a wire of a diameter greater than the maximal diameter; and
reducing the diameter of the wire to less than the preselected diameter.

2. The method of Claim 1, wherein step of reducing comprises center-less grinding.

3. The method of Claim 1, further comprising the step of coating at
0 least a portion of the mandrel with a hydrophilic coating.

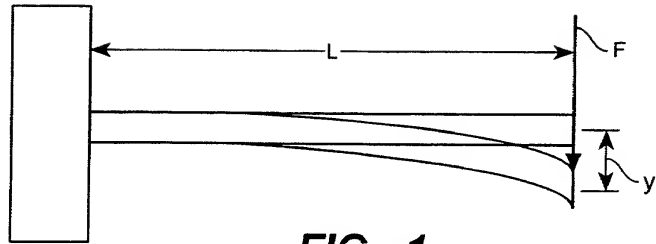
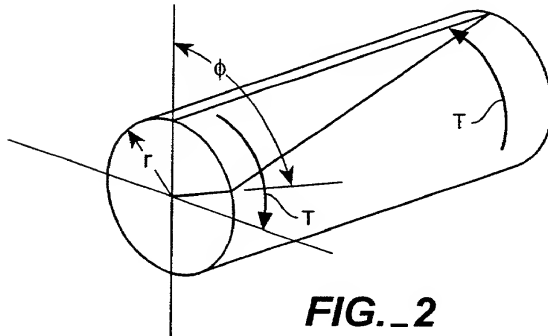
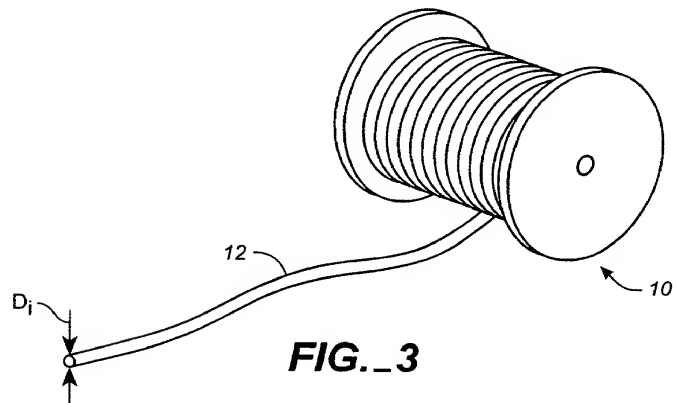
4. The method of Claim 1, further comprising the step of affixing a
coil to the mandrel.

5. The method of Claim 4, wherein the coil is radiopaque.

6. The method of Claim 1, wherein the step of providing comprises
5 unwinding the wire from a spool.

7. The method of Claim 6, further comprising the step of
straightening the unwound wire.

1 / 3

**FIG._1****FIG._2****FIG._3**

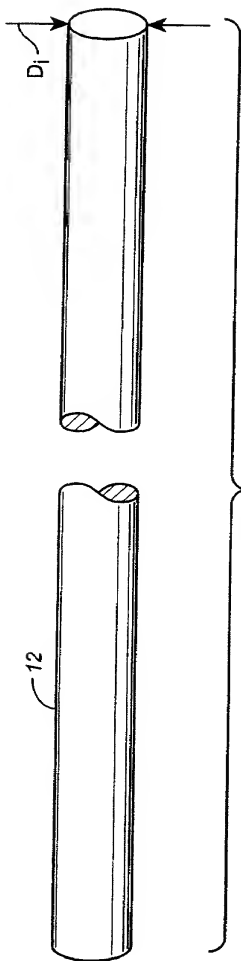


FIG. 4

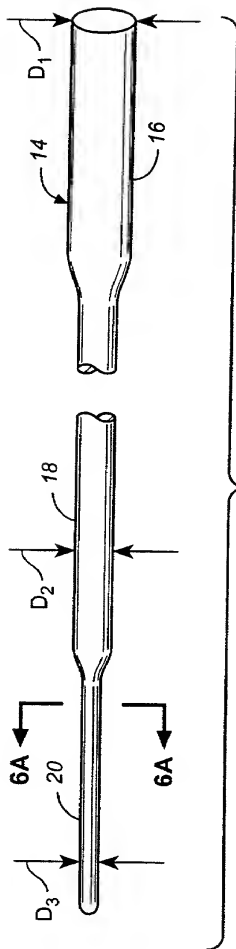
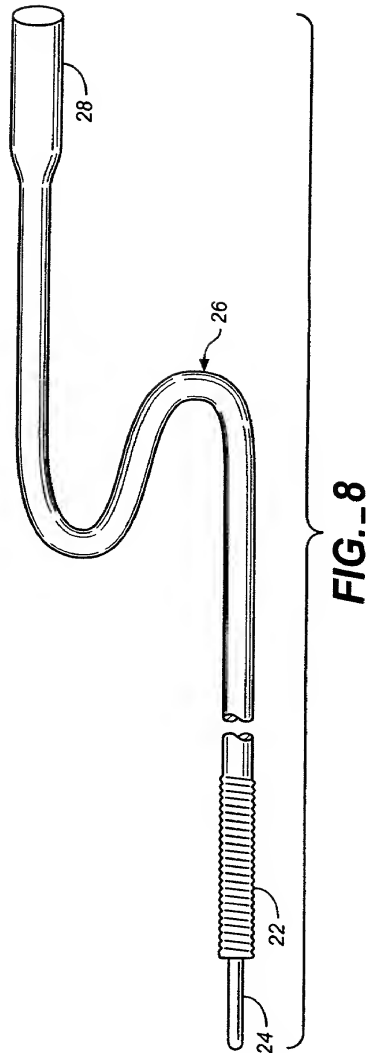
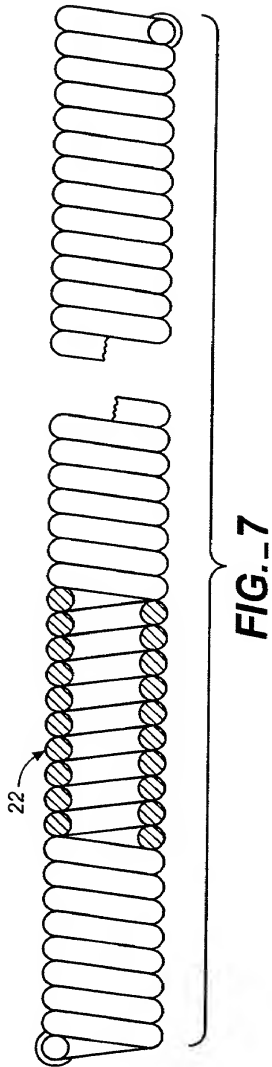


FIG. 5



FIG. 6A

FIG. 6B



COMBINED DECLARATION FOR PATENT APPLICATION AND POWER OF ATTORNEY
(Includes Reference to Provisional and PCT International Applications)

Attorney's Docket No.

018413-331

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name;

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

Improved Guidewire

the specification of which (check only one item below):

☐ is attached hereto.

☒ was filed as United States application

Number 09/806,946

on April 6, 2001

and was amended

on _____ (if applicable).

☐ was filed as PCT international application

Number _____

on _____

and was amended

on _____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose to the Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, §1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, §119 (a)-(e) of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed:

PRIOR FOREIGN/PCT APPLICATION(S) AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. §119:

COUNTRY (if PCT, indicate "PCT")	APPLICATION NUMBER	DATE OF FILING (day, month, year)	PRIORITY CLAIMED UNDER 35 U.S.C. §119
PCT	PCT/US99/29329	09 December 1999	X_ Yes _ No
			_ Yes _ No
			_ Yes _ No
			_ Yes _ No
			_ Yes _ No

I hereby claim the benefit under Title 35, United States Code § 119(e) of any United States provisional application(s) listed below.

60/111,892

(Application Number)

10 December 1998

(Filing Date)

(Application Number)

(Filing Date)

COMBINED DECLARATION FOR PATENT APPLICATION AND POWER OF ATTORNEY (CONT'D)
(Includes Reference to Provisional and PCT International Applications)

Attorney's Docket No.

018413-331

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) or PCT international application(s) designating the United States of America that is/are listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in that/those prior application(s) in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose to the Office all information known to me to be material to the patentability as defined in Title 37, Code of Federal Regulations §1.56, which became available between the filing date of the prior application(s) and the national or PCT international filing date of this application:

PRIOR U.S. APPLICATIONS OR PCT INTERNATIONAL APPLICATIONS DESIGNATING THE U.S. FOR BENEFIT UNDER 35 U.S.C. §120:

U.S. APPLICATIONS		STATUS (check one)		
U.S. APPLICATION NUMBER	U.S. FILING DATE	PATENTED	PENDING	ABANDONED
PCT APPLICATIONS DESIGNATING THE U.S.				
PCT APPLICATION NO.	PCT FILING DATE	U.S. APPLICATION NUMBERS ASSIGNED (if any)		
PCT/US99/29329	09 December 1999			

I hereby appoint the following attorneys and agent(s) to prosecute said application and to transact all business in the Patent and Trademark Office connected therewith and to file, prosecute and to transact all business in connection with international applications directed to said invention:

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Platon N. Mandros 22,124
Benton S. Duffett, Jr. 22,030
Norman H. Stepno 22,716
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Allen R. Baum 36,086
Brian P. O'Shaughnessy 32,747
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Wendi L. Weinstein 34,456
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21839

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21839

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Alexandria, Virginia 22313-1404

Address all telephone calls to: Gerald F. Swiss at (650)622-2300.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

COMBINED DECLARATION FOR PATENT APPLICATION AND POWER OF ATTORNEY (CONT'D)
(Includes Reference to Provisional and PCT International Applications)

Attorney's Docket No.

018413-331

1-00
FULL NAME OF SOLE OR FIRST INVENTOR

Mark P. Ashby

SIGNATURE

Mark P. Ashby

DATE

5-30-01

RESIDENCE

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CITIZENSHIP

United States of America

POST OFFICE ADDRESS

Same as above

2-00
FULL NAME OF SECOND JOINT INVENTOR, IF ANY

Brian M. Strauss

SIGNATURE

Brian M. Strauss

DATE

5/24/01

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20592 Porter Ranch Road, Trabuco Canyon, CA 92679 CA

CITIZENSHIP

United States of America

POST OFFICE ADDRESS

Same as above